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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,042	04/21/2004	Trevor Barrowcliffe	674583-2001	7419

20999 7590 09/02/2009
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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
09/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,042	BARROWCLIFFE, TREVOR	
	Examiner	Art Unit	
	HOPE A. ROBINSON	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,13-15 and 18-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-8, 13-15 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/17/08, 6/17/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 17, 2009 has been entered.

2. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1652.

Claim Disposition

3. Claims 19-22 have been added. Claims 1, 3-8, 13-15 and 18-22 are pending and are under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3-8, 13-15, and 18-22 rejected under 35 U.S.C. 103(a) as being obvious over Barrowcliffe et al. (1981, Thromb. Res. Vol.21, page 181, cited on IDS) in view of Lang et al. (U.S. 5,506,112) taken with Capon et al. (U.S. 4,965,199).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer

in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Barrowdliffe et al. found that FEIBA contained a form of Factor VIII that contributed 30% to 50% of the overall in vitro clot-promoting activity in inhibitor plasma. The results suggested that the Factor VIII may exist as a complex with Factor IXa and phospholipid and in this form may be partially protected from interaction with inhibitors. Barrowcliffe et al. also reported that the addition of purified Factor IXa and phospholipid could protect Factor VIII from subsequent inactivation by antibody and that the major protective effect was provided by the phospholipid (admitted prior art, see paragraph [0012] of the instant specification. Barrowcliffe et al. does not *per se* teach a kit.

Lang et al. teach a method where a mixture of factor IXa, and phospholipids is added to a sample containing factor VIII (aqueous), thus activating factor VIII to be assayed; and where subsequently activated factor VIII forms complex with factor IXa (see column 1, lines 8-14) and Capon et al. teach a kit and a method involving a step where factor IXa initiates the conversion of factor X to the activated form, factor Xa; where factor VIII is currently believed to function as a cofactor and is required to enhance the activity of factor IXa. This step in the cascade is critical, since two most common hemophilia disorders have been determined to be caused by the decreased functioning of either factor VIII (hemophilia A or classic hemophilia) or factor IXa (hemophilia B). Therefore, factor VIII is capable of catalyzing the conversion of factor X to Xa in the presence of factor IXa as well as correcting the coagulation defect in

plasma derived from hemophilia A affected individuals (see column 10, lines 27-32). Claim 8 is included in this rejection because it depends from rejected independent base claim 4. Lang et al. does not per se teach an injectable form. However, Capon et al. teach a composition that is free of contaminants, intended for a medicament to treat Hemophilia patients.

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole, a method of treating hemophilia and a kit as recited in the claims because Barrowcliffe disclose the combination to FVIII and FIXa and the incentive to do so and Lang teach the same combination and the intention of using same as a medicament. Moreover, Capon, teaches FVIII and FIXa in combination and in a kit. One of ordinary skill in the art would be motivated to combine the teachings of the reference because each reference combines FVIII and FIXa and provide reasoning for said mixture being useful in the art. Furthermore, although Lang et al. does not expressly teach a kit, the art generally recognizes that a kit is simply ease of a method. Therefore, the claimed invention is prima facie obvious.

Response to Arguments

5. Applicant's comments have been considered in full. Note that the rejections/objections of record are withdrawn. Thus applicant's comments are moot and will not be discussed herein. Note that a new ground of rejection has been instituted as set forth above under 35 USC 103. The Capon and Lang references remain relevant because "treating of hemophilia" represents an intended use only, and the method only

requires administering factor VIII and IXa. Capon teaches that factor VIII is capable of catalyzing the conversion of factor X to Xa in the presence of factor IXa, as well as correcting the coagulation defect in plasma derived from hemophilia A affected individuals (see column 10, lines 27-32). Also, Figure 1 of Capon shows that the surface-mediated activation of blood coagulation requires factor IXa and factor VIII. Therefore, factor VIII and factor IXa both take part in the cascade reaction of surface mediated activation of blood coagulation and the presence of coagulation factor IXa allows the concentration of coagulation factor VIII in the composition to be reduced in comparison to a composition which does not comprise a coagulation factor IXa (see the language claimed in the instant claim 4). Therefore, Capon teaches the method of treating hemophilia since the method claimed requires only the presence of factor VIII and factor IXa and the method claimed requires only one step. Further, examiner states that the presence of factor IXa will necessary potentiate the activity of low concentrations of factor VIII since this is an inherent characteristics of the interaction of factor IXa with factor VIII, for example. Therefore, the rejection is proper and is thus maintained.

Conclusion

6. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652